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| 08/150,000 | 09/17/98 | KALTENBACH | P 10980096-1 |

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 12/20/99

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/156,804

Applicant(s)

Kaltenbach et al.

Examiner

Patricia Kathryn Bex

Group Art Unit

1743



☒ Responsive to communication(s) filed on Aug 2, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-25 is/are pending in the applicat

Of the above, claim(s) 13-24 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 and 25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12 and 25, drawn to a modular microchannel apparatus, classified in class 422, subclass 68.1.
 - II. Claim 13, drawn to a modular microchannel apparatus, classified in class 422, subclass 100.
 - III. Claims 14-21, drawn to a method of making a modular microchannel apparatus, classified in class 219, subclass 121.6.
 - IV. Claims 22-24, drawn to a method of using a modular microchannel apparatus, classified in class 436, subclass 177.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the powering plate and peltier plate is not necessary for the apparatus to perform as a modular microchannel for the analysis of an analyte. The subcombination has separate utility such as a microcentrifuge for mixing reagents and a fluid sample.

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3. Inventions I and III, II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making a microchannel of group III can be used to form an apparatus used for mixing a fluid sample.

4. Inventions I and IV, II and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of group IV can be used to mix a sample introduced into the separation unit.

5. Inventions III and IV are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Philip Yip on December 7, 1999 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12 and 25.

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Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Drawings

8. The drawings are objected to under 37 CFR 1.83(a) because they fail to show Figure 7 as described in the specification on page 10 line 14. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Correction is required.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 106a. Correction is required.

Claim Objections

10. Claim 5 is objected to because of the following informalities: change “regent” to “reagent” in line 3 of claim. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claim 10, it is vague and indefinite as to what the phrase “operatively modularly operatively coupling” is referring to.

In reference to claim 12, it is unclear as to what applicant means on the last line of claim 12, “the surrounding”.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 1- 4, 6-7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410).

Swedberg teaches a separation unit 2 including a microchannel, in which the analyte can be driven to pass through the microchannel 10 due to molecular characteristics thereof, the time for the analyte to pass through the microchannel being indicative of the molecular characteristics of the analyte and a reservoir unit having one or more reservoirs having dimensions compatible with the separation unit for coupling operatively modularly with the separation unit to supply liquid reagents thereto (column 29 lines 47-56). However, Swedberg does not explicitly state that the reservoirs are prepackaged liquid reagents therein before the reservoir unit is coupled with the separation unit. It would have obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg prepackaged liquid reagents, in order to ensure that the reagents avoid contamination before introduction in the microchannel.

16. Claims 5 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) and Kambara et al. (USP 5,968,331).

Swedberg as disclosed above, does not teach an apparatus wherein the reservoir unit includes a membrane covering at least one of the reservoirs confining the prepackaged liquid reagent therein, the membrane being penetratable with a probe, the probe being used for applying

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a driving force to drive movement of chemicals from the reservoir through the microchannel.

Kambara does teach a reservoir unit 53 containing a liquid and being penetratable with probes 54, where the probes 54 used for applying a driving force to drive chemicals from the reservoir through the microchannel 15 (column 8 lines 4-40). It would have obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg probes to drive liquid into the microchannels, in order to reduce the time and labor needed to introduce the liquids in the microchannels, such as the case when microsyringes are used (column 1 lines 60-63). However, Kambara does not teach a membrane covering at least one of the reservoirs confining the prepackaged liquid reagent therein, through which the probe would penetrate. However, it would have obvious to one skilled in the art at the time of the invention to have included in the apparatus of Kambara a membrane covering at least one of the reservoirs confining the prepackaged liquid reagent therein, through which the probe would penetrate, in order to ensure that the reagents would avoid diffusion into the microchannels before the introduction of the probes to ensure proper flow through the microchannels.

17. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (USP 5,571,410) in view of Kaltenbach et al. (USP 5,641,400).

Swedberg as disclosed above, does not teach an apparatus comprising a peltier plate coupled to the separation chip for controlling the temperature thereof. However, Kaltenbach does teach a peltier plate for coupling to the separation chip for controlling the temperature thereof (column 20 lines 37-67 and column 21 lines 1-37, Figures 9A-10B). It would have


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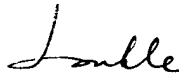
obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg a peltier plate coupled to the separation chip, in order to influence many of the physical and chemical parameters involved in separation techniques and decrease the time needed to perform the separation. The temperature can affect the sample stability, buffer viscosity, chemical equilibria, pH and the resulting migration time for a given chemical species (column 3 lines 9-21).

Conclusion

18. Claims 1-12 and 25 are rejected.
19. References: Chow et al., Kovacs, Halvorsen and Mathies et al. are cited as art of interest for the teachings of an apparatus containing a separation unit which includes a microchannel for separation of an analyte.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Kathryn Bex whose telephone number is (703) 306-5697.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


Patricia Kathryn Bex
Patent Examiner
Group Art Unit 1743
December 10, 1999


LONG V. LE
PRIMARY EXAMINER
DU. 1743

pkb